JUL 07 2000

Rochester MEDICAL

13.0 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Submitter and Contact Person: Mary M. Wilen
Rochester Medical Corporation

Name of the Device:
Classification Name: Urological Catheter
Proprietary Name: Release NF® Antibacterial Foley Catheter
Antibacterial Personal® Catheter

Predicate Devices:
Rochester Medical All Silicone Foley Catheter K981612
Rochester Medical Personal® Catheter K970704 & K000723
Release NF® Antibacterial Foley Catheter K971627

Intended Use of the Device

Release NF Antibacterial Foley Catheter
For urological use only. The Antibacterial Catheter is intended for short term use to provide urinary bladder drainage in adult males and females requiring catheterization for surgical procedures, monitoring urine output, management of incontinence and voiding dysfunction. The Catheter has been shown to provide a statistically significant reduction in the incidence of catheter acquired bacterial urinary tract infection during the first 5 days of catheterization. It is not intended as a treatment for active urinary tract infection.
Antibacterial Personal Catheter
For urological use only. The Antibacterial Personal Catheter is intended for urinary bladder drainage in adult males and females requiring catheterization for management of incontinence, voiding dysfunction and surgical procedures. Efficacy of the Antibacterial Personal Catheter in preventing urinary tract infection during intermittent use has not been shown. It is not intended as a treatment for active urinary tract infection.

Device Description
The Release NF Foley Catheter consists of standard Two and Three-Way Foley catheters with an antibacterial coating. They are available in adult male and female lengths, French sizes from 12 to 26 and balloon sizes 5, 10 and 30cc.

The Antibacterial Personal Catheter consists of a single lumen catheter with an antibacterial coating. It is available in male and female lengths and French sizes 12 through 18.

One Rochester Medical Drive Stewartville, MN 55976 ISO 9001 CERTIFIED Tel: (507) 533-9600 Fax: (507) 533-9726

Technological Characteristics

The catheters described in the 510(k) have similar technological and performance characteristics to the predicate devices. All of the catheters are manufactured using similar processes. The catheters are constructed from silicone elastomers and have an antibacterial coating. The predicate devices are manufactured from the same materials. The catheters are supplied in French sizes ranging from 12 to 26 and balloon capacities of 5, 10 and 30cc. The predicate devices are available in the same sizes but not all sizes are offered with the antibacterial coating. The device is supplied in male and female lengths. The predicate devices are supplied in male and female lengths. All of the devices are supplied sterile for single use.

Testing and Results

Rochester Medical Corporation Release NF Antibacterial Foley and Antibacterial Personal Catheter have been tested to and meet the following test requirements.

Rochester Medical Dimensional Specifications
Rochester Medical Antibacterial Content Specification
RMC Process Instruction IINS3019 Tensile Strength/Elongation
ASTM 623 F 98 Standard Performance Specification for Foley Catheter:

Foley Catheters:
ASTM 623-89 Section 5.1 Flow rate through the drainage lumen
ASTM 623-89 Section 5.2 Balloon integrity/resistance to rupture
ASTM 623-89 Section 5.3 Inflated balloon response to pullout*
ASTM 623-89 Section 5.4 Balloon volume maintenance
ASTM 623-89 Section 5.5 Balloon size and shaft size**
ASTM 623-89 Section 5.6 Deflation reliability, failure to deflate

EN 1616: 1997 Sterile urethral catheters for single use

Foley Catheters:
EN 1616: 1997 Annex A. Strength of catheter
EN 1616: 1997 Annex B. Security of fit of the drainage funnel.
EN 1616: 1997 Annex C. Balloon Security
EN 1616: 1997 Annex D. Inflation and or balloon deflation
Personal Catheter:
EN 1616: 1997 Section 4.8 Flow rate

* The 26 French catheter could not be tested because it would not fit through the 28 French orifice of the test fixture. (See below for information on catheter tip diameters.) All other catheters tested met this requirement.
** Due to the proprietary manufacturing process that allows Rochester Medical to manufacture catheters with balloons that are incorporated into the catheter wall rather than being applied during a secondary operation, the tip diameter is equivalent to the balloon diameter. All balloon diameters comply with the standard.

Aged Product Testing:

Testing of products aged under ambient and accelerated conditions indicate that there are no adverse effects on device materials or performance characteristics.

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Release NF® Foley Catheter and Antibacterial Personal® Catheter
K001143 Supplement - 6/29/2000
Shelf Life Testing

Release NF® Foley Catheter
Rochester Medical intends to label a 4 year shelf life on the Release NF Antibacterial Foley catheter based on the results of testing of product smples that have been aged under ambient conditions for 4 years. The testing included functional test in accordance with ASTM 623-89, sterility testing, dimensional measurements in accordance with the product specification and testing for Nitrofurazone stability and content. A copy of the test plan and 4 year report are attached. All of the product samples met the test acceptance criteria with one exception. One of five samples tested was below specification for total nitrofurazone content. However as described in the test report, this was determined to be related to the manufacturing process rather than an effect of ageing.

Antibacterial Personal® Catheter
Shelf life for the Antibacterial Personal Catheter is derived from shelf life testing of the Release NF Foley Catheter and the standard Personal Catheter (K000723). Testing of these devices can be applied to the Antibacterial Personal Catheter because the (1) Antibacterial Personal Catheter and the Release NF Foley Catheter are both coated with the identical antibacterial coating consisting of a primer coat of 4720 silicone and a mixture of 4720 silicone and nitrofurazone and (2) the uncoated Antibacterial Personal Catheter and the standard Personal Catheter are made with identical materials.

As noted above, a 4 year shelf life has been established for the Release NF Foley Catheter. Shelf life testing for the Personal Catheter included in K000723 consisted of dimensional, tensile strength and flow rate testing of samples that were aged under ambient and accelerated conditions. This testing supported labeling the Personal Catheter with a 25 month shelf life. (See test report in K000723) Based on this testing Rochester Medical intends to place a 25 month shelf life on the Antibacterial Personal Catheter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 07 2000

Ms. Mary M. Wilen
Director of Clinical and
Regulatory Affairs
Rochester Medical Corporation
One Rochester Medical Drive
Stewartville, MN 55976

Re: K001143
Release NF® Antibacterial Foley Catheter
Antibacterial Personal® Catheter
Dated: April 7, 2000
Received: April 10, 2000
Regulatory Class: II
21 CFR §876.5130/Procode: 78 MJC

Dear Ms. Wilen:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

510(k) NUMBER (if Known): K001143

DEVICE NAME: **Antibacterial Personal® Catheter**

INDICATIONS FOR USE:

For urological use only. The Antibacterial Personal Catheter is intended for urinary bladder drainage in adult males and females requiring catheterization for management of incontinence, voiding dysfunction and surgical procedures. Efficacy of the Antibacterial Personal Catheter in preventing urinary tract infection during intermittent use has not been shown. It is not intended as a treatment for active urinary tract infection.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K001143

(Optional Format 1/2/96)

510(k) NUMBER (if Known): K001143

DEVICE NAME: Release NF® Antibacterial Foley Catheter

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K001143

(Optional Format 1/2/96)